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C. R. Bard, Inc. and
Bard Peripheral Vascular, Inc.

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation

No. 2:15-MD-02641-DGC

DEFENDANTS C. R. BARD, INC. AND BARD PERIPHERAL VASCULAR, INC.'S RESPONSE IN OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE OPINIONS AND TESTIMONY OF CHRISTOPHER S. MORRIS, M.D.

(Assigned to the Honorable David G. Campbell)

(Oral Argument Requested)

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Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively "Bard") respectfully respond to Plaintiffs' Motion to Exclude Opinions and Testimony of Christopher S. Morris, M.D. ("Motion").

In their Motion, Plaintiffs on eight occasions assert that Dr. Morris's opinions are "*ipse dixit*," as if repeatedly invoking that term transforms their Motion into a meritorious *Daubert* motion. (*See* Pls. Mot. at 2, 3, 8, 10, 15, 16.) Plaintiffs are wrong. Dr. Morris's methodology is sound. His opinions are based on over 25 years of clinical experience as a practicing interventional radiologist, and they are informed and are directly supported by the medical literature. Employing the same rigorous, scientific, and intellectual inquiry into the issues in this case as he does in his clinical practice, Dr. Morris assessed the issues, considered the available medical literature (including contradictory opinions in the literature), and reached his conclusions and opinions. Plaintiffs may disagree with those opinions, but that is no basis to exclude his opinions under *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993) ("*Daubert I*"). Accordingly, for the reasons that follow, Plaintiffs' Motion should be denied.

MEMORANDUM OF POINTS AND AUTHORITIES

I. INTRODUCTION AND FACTUAL BACKGROUND

Dr. Morris is a leading, practicing interventional radiologist with over 25 years of clinical experience. (*See* Dr. Morris MDL Report, attached as Exhibit A, at 1.) His clinical practice includes a large variety of vascular and non-vascular procedures spanning the gamut of interventional radiology. (*See id.* at 2.) He estimates that he has implanted more than 800 IVC filters over his career. (*See id.*) Dr. Morris has implanted filters manufactured by a variety of medical device companies, including Bard's IVC filters, which Dr. Morris states have been the "most popular" optional IVC filters at his practice over the past 13 years. (*See id.* at 3-4.) Dr. Morris and his team have placed approximately 200 to 300 Bard IVC filters.[1] (*See* Dr. Morris Dep. Tr. (July 25, 2017), attached as Exhibit

[1] Plaintiffs attempt to discredit Dr. Morris by claiming he has an "undeniable bias" due to "a longstanding commercial relationship with Bard to help the company promote its products." (*See* Pls. Mot. at 1 n.2.) But Plaintiffs fail to point out that Dr. Morris has not

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B, at 109:22 to 110:5.)

Dr. Morris is also Professor of Radiology and Surgery at the College of Medicine at the University of Vermont, where he teaches students, residents, and fellows about IVC filters. (*See* Ex. A, MDL Report at 1.) At the national meeting of the Society of Interventional Radiology ("SIR"), he taught practicing interventional radiology colleagues about IVC filters at SIR's IVC filter workshop series for five years, and he was chair of the workshop for three years. (*See id.* at 1-2.) Importantly, long before Dr. Morris became involved as an expert in this litigation, Dr. Morris researched, studied, and published regarding IVC filters. (*See id.* at 2, 29 & Refs. 1-6.) This work includes assessing methods for clinical follow-up of patients with IVC filters, with the goal of increasing filter retrieval rates. (*See id.* at 2.) Dr. Morris recently published on the IVC filter follow-up protocol that his practice has used since approximately 2007. (*See* Ex. B, Morris Dep. at 112:9 to 113:3; Winters, *et al.*, *A Multidisciplinary Quality Improvement Program Increases the Inferior Vena Cava Filter Retrieval Rate*, 22(I) Vasc. Med. 51-56 (2017), attached as Exhibit C.)

Dr. Morris's full opinions are set forth in his Rule 26 Report, and Plaintiffs explored those opinions in detail in his deposition given on July 25, 2017. Dr. Morris offers the following opinions that are relevant to Plaintiffs' Motion:

First, in response to Plaintiffs' experts' opinions about Bard's IVC filters, Dr. Morris opines that Bard's IVC filters are safe and effective. (*See* Ex. A, MDL Report at 21.) He bases this opinion on his review of the available medical literature and on his personal experience using Bard's retrievable filters over the years. (*See id.*) Dr. Morris responds to Plaintiffs' experts' reliance on several cherry-picked medical articles about purported rates of complications with Bard's retrievable IVC filters by identifying weaknesses in those studies' designs, methodologies, and conclusions. (*See id.* at 25-26.)

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been a consultant for Bard or any other manufacturer since 2006 and that he spent no more than three years as a consultant for Bard. (*See* Ex. B, Morris Dep. Tr. at 46:5-10.)

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And regarding Plaintiffs' experts' reliance on the MAUDE database, Dr. Morris identifies certain of the recognized limitations and weaknesses of MAUDE. (*See, e.g.*, *id.* at 21.)

Second, in response to Plaintiffs' experts' opinions that every patient with a Bard IVC filter needs to receive routine medical imaging via a non-contrast computed tomography ("CT") scan merely to check the status of the filter, Dr. Morris opines that, in an otherwise asymptomatic patient, medical imaging does not play a role in the on-going decision of whether a retrievable IVC filter is still medically indicated for the prevention of pulmonary embolism. Specifically, Dr. Morris states that "in an asymptomatic patient with an IVCF, the status of an IVCF has no bearing on whether or not it should be removed, as that decision is based on clinical parameters, including the risk to benefit ratio for each individual patient. Therefore, imaging does not contribute to the clinical decision on whether or not to remove an IVCF." (*Id.* at 15.) But, "[i]f a patient with an IVCF has a symptom at any time, such as abdominal pain, then a contrast enhanced CT scan may be warranted, not a non contrast enhanced CT scan." (*Id.*) Dr. Morris's opinions are consistent with the prevailing medical literature, including the recently published SIR Practice Parameter, which states that patients with retrievable IVC filters "should be clinically reassessed periodically to weigh the benefits of continued filtration (need for PE prophylaxis) against the associated risks." (*2016 Revised ACR--SIR--SPR Practice Parameter for the Performance of Inferior Vena Cava (IVC) Filter Placement for the Prevention of Pulmonary Embolism* ("2016 SIR Practice Parameters"), attached as Exhibit D, at 2.) His opinions also are consistent with the FDA's 2014 Safety Communication about retrievable IVC filters, which states that doctors responsible for the follow-up care of IVC filter patients should "consider the risks and benefits of filter removal for each patient." (*See* FDA 2014 Safety Communication, attached as Exhibit E.) Notably, neither the 2016 SIR Practice Parameters nor the FDA recommends that patients receive routine medical imaging simply to assess the status of a patient's filter.

Third, Dr. Morris offers opinions regarding the standard of care for retrieval of IVC filters. (*See* Ex. A, MDL Report at 4-7.) His opinion, which is supported by the

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medical literature, is that a retrievable IVC filter "is most easily removed within the first year after placement." (*Id.* at 4.) Dr. Morris opines that after that period, the filter over time may adhere to the wall of the IVC, or it may otherwise make it difficult to be retrieved. (*See id.* at 4-5.) While Dr. Morris recognizes that various "advanced techniques" are potentially available to retrieve a filter in complex cases, he notes that the long-term effect of IVC trauma caused by those techniques is not known. (*See id.* at 5.) Thus, particularly in circumstances where a patient is not experiencing any symptoms related to his or her IVC filter, the risk of attempting to remove a filter after one year may outweigh the benefits. (*See* Dr. Morris Class Action Report, attached as Exhibit 1 to Pls. Mot., at 12.)

II. ARGUMENT AND CITATION OF AUTHORITY

To be admissible, a qualified experts' opinions must be reliable, be based on sufficient facts or data, and "fit" the case. *See, e.g.*, Fed. R. Evid. 702; *Daubert I*, 509 U.S. at 591. Plaintiffs do not question Dr. Morris's qualifications as an expert in the field of interventional radiology or use of IVC filters, nor do Plaintiffs argue that his opinions lack proper "fit." (*See generally* Pls. Mot.) Instead, Plaintiffs purport to focus on the reliability element of *Daubert*, although Plaintiffs misapply it.

A. Dr. Morris Bases His Opinions on Sound Methodology.

1. Dr. Morris Appropriately Relies on His Experience and on Medical Literature to Form His Opinions.

This Court has recognized that a medical doctor may rely on his or her training and experience to form the basis of reliable opinions under *Daubert*. *See Tavilla v. Cephalon Inc.*, No. CV11-0270 PHX DGC, 2012 WL 1190828, at *4 (D. Ariz. Apr. 10, 2012) (finding that medical doctor's reliance on his "substantial" experience in addiction medicine rendered his opinions reliable); *see also In re Mirena IUD Prod. Liab. Litig.*, 169 F. Supp. 3d 396, 420–21 (S.D.N.Y. 2016) ("Dr. Goldberg's experience as a medical doctor specializing in OB/GYN and his familiarity and experience in placing and teaching how to place IUDs . . . are indicative of the reliability of his opinions."); *In re Fosamax*

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Prod. Liab. Litig., 645 F. Supp. 2d 164, 181 (S.D.N.Y. 2009) (doctors' clinical experience is "highly indicative of the reliability of their opinions"). *Cf. Primiano v. Cook*, 598 F.3d 558, 565 (9th Cir. 2010) ("Especially when a relevant experience base is unavailable, physicians must use their knowledge and experience as a basis for weighing known factors along with the inevitable uncertainties to mak[e] a sound judgment." (internal quotation marks omitted) (alteration in original)). Additionally, a doctor may rely on relevant medical literature to inform his or her opinions. *See, e.g., In re Mirena*, 169 F. Supp. 3d at 412 ("[A] review of other studies and scientific literature can be enough . . . to make that proposed testimony reliable."). And, when a doctor relies on his or her medical experience and—using the backdrop of peer-reviewed literature as a guide—renders an opinion in a case, the opinion is reliable because it "is the ordinary methodology of evidence based medicine." *Primiano*, 598 F.3d at 567; *see also Deutsch v. Novartis Pharm. Corp.*, 768 F. Supp. 2d 420, 480-81 (E.D.N.Y. 2011) (allowing medical doctors to testify where they based their opinions on their own experiences and review of literature).

Dr. Morris employed this precise methodology in this case. His opinions regarding the safety and efficacy of Bard's retrievable IVC filters are based on his years of experience implanting hundreds of Bard IVC filters, (*see* Ex. B, Morris Dep. at 109:22 to 110:5), as well as on the relevant medical literature regarding those devices. (*See* Ex. A, MDL Report at 25-27.) Similarly, his opinions regarding appropriate patient follow-up protocols—including the lack of need for asymptomatic patients to undergo routine medical imaging, such as a CT scan, merely to check on the status of their IVC filters—are based on his institution's own practice that has been in place for approximately 10 years. (*See* Ex. B, Morris Dep. at 112:9 to 113:3.) Those opinions are also based on a wide body of literature. (*See* Ex. A, MDL Report at 12 & Refs. 6, 53-62 (referencing 12 studies regarding IVC filter follow-up programs, none of which include routine, pre-removal CT scans or other medical imaging[2]).)

[2] One of these 12 studies was written by Northwestern University colleagues of Plaintiffs' experts Drs. Robert Vogelzang and Kush Desai. (*See* Karp, *et al.*, *A Dedicated Inferior Vena Cava Filter Service Line: How to Optimize Your Practice*, 33 Semin. Intervent.

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The fact that Dr. Morris's opinions in this case arise from his clinical experience and research using Bard's IVC filters is particularly probative in demonstrating the reliability of his opinions. As the Ninth Circuit Court of Appeals stated, "[o]ne very significant fact to be considered is whether the experts are proposing to testify about matters growing naturally and directly out of research they have conducted independent of the litigation." *Daubert v. Merrell Dow Pharm., Inc.*, 43 F.3d 1311, 1317 (9th Cir. 1995) ("*Daubert II*"). "[I]n determining whether proposed expert testimony amounts to good science, we may not ignore the fact that a scientist's normal workplace is the lab or the field, not the courtroom or the lawyer's office." *Id.* Thus, where an expert testifies based his own research independent of the litigation, that is "objective proof that the research comports with the dictates of good science." *Id.*

Dr. Morris's opinions clearly grow "naturally and directly" out of his practice and research conducted independent of this litigation. His published research and work regarding IVC filters dates back to the late 1980s. (*See* Ex. A, MDL Report at 2 & Refs. 1-6.) Moreover, his opinions regarding appropriate follow-up care for patients with retrievable IVC filters are based on the protocol used at his medical practice since 2007, which was published this year. (*See* Ex. B, Morris Dep. at 112:9 to 113:3; Ex. C, Winters, *et al.*) Thus, it is beyond reasonable dispute that Dr. Morris has employed a sound methodology of reaching his opinions based on his extensive medical experience and analysis of the applicable medical literature.

2. Dr. Morris Appropriately Considered Contradictory Medical Literature.

Plaintiffs argue that Dr. Morris's opinions are somehow unreliable because he allegedly "subjectively disagrees" with the conclusions of certain medical literature regarding alleged complication rates with Bard IVC filters and regarding the theory that

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Radiol. 105-08 (2016), attached as Exhibit F.) The monitoring program as described in the article does not include routine medical imaging to check the status of a patient's filter. (*See id.* at 107.)

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complication rates will increase over time the longer a device is implanted. (Pls. Mot. at 7.) Plaintiffs' argument is misplaced.

Dr. Morris reviewed and assessed various articles on which Plaintiffs rely that purportedly show increased complication rates with Bard's IVC filters and/or increased complication rates over time, including An, *et al.*,[3] Tam, *et al.*,[4] and Nicholson, *et al.*[5] (*See* Ex. A, MDL Report at 25-26.) Regarding An, *et al.*, Dr. Morris points out that the authors may have inappropriately used numerators and denominators with different prevalence calculations (five-year period prevalence versus five-year point prevalence), rendering the fracture rate allegedly found in the study "artificially high." (*See id.* at 25-26.) Regarding Tam, *et al.*, Dr. Morris notes that Kaplan-Meier survival estimates from the study are unreliable because of the numerous censored events. (*See id.* at 25.) And regarding Nicholson, *et al.*, Dr. Morris notes that selection bias may have limited the results of an already very small study. (*See id.* at 26.)[6] These are but a few of the many flaws in those studies identified by Dr. Morris.

The MDL judge in *In re Mirena* found this precise methodology appropriate. There, the plaintiffs moved to exclude a doctor because she ignored contradictory scientific literature. *See In re Mirena*, 169 F. Supp. 3d at 419. The court found this argument "unfounded" because the expert "specifically addressed the leading study on which Plaintiffs rely" and "found it to suffer 'from multiple methodological and analytical flaws that render its conclusions inaccurate.'" *Id.* (quoting the expert's report). Because

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[3] *Prevalence and clinical consequences of fracture and fragment migration of the Bard G2 filter: imaging and clinical follow-up in 684 implantations*, 25 J. Vasc. Interv. Radiol. 941-948 (2014), attached as Exhibit 7 to Plaintiffs' Motion.

[4] *Fracture and distant migration of the Bard Recovery filter: a retrospective review of 363 implantations for potentially life-threatening complications*, 23 J. Vasc. Interv. Radiol. 199-205 (2012), attached as Exhibit 8 to Plaintiffs' Motion.

[5] *Prevalence of fracture and fragment embolization of Bard retrievable vena cava filters and clinical implications including cardiac tamponade*, 170 Arch. Intern. Med. 1827-31 (2010), attached as Exhibit 9 to Plaintiffs' Motion.

[6] Dr. Nicholson himself recognized flaws in his study. (*See* Nicholson, *Correction to Article About Prevalence of Fracture and Fragment Embolization of Bard Retrievable Vena Cava Filters*, 172 Arch. Intern. Med. 972 (June 2012), attached as Exhibit G.)

"the parties so vehemently disagree on [the study's] credibility, it is a suitable topic for cross-examination before a jury." *Id.*

Like the expert in *In re Mirena*, Dr. Morris analyzed contradictory literature and identified various "methodological and analytical flaws that render [their] conclusions inaccurate." *Id.* This is sound science that is not grounds for exclusion under *Daubert*.[7]

3. Dr. Morris Appropriately Did Not Review or Rely on Internal Company Documents to Form His Opinions.

Plaintiffs argue that Dr. Morris's opinions are unreliable because he did not consider internal company documents in formulating his opinions, even though as a practicing medical doctor, he has never seen those types of documents. (Pls. Mot. at 8-10.) Again, Plaintiffs' arguments are misplaced.[8]

Under Federal Rule of Evidence 702(b), an expert must rely on "sufficient facts or data," which includes information of the type that "experts in the particular field would reasonably rely on." Fed. R. Evid. 703; *see also In re Toyota Motor Corp. Unintended Acceleration Mktg., Sales Practices, & Prod. Liab. Litig.*, 978 F. Supp. 2d 1053, 1066 (C.D. Cal. 2013) (noting that experts' opinions must "be premised upon 'sufficient facts or data' of the type generally relied upon by experts in the relevant field"); *Stone v.*

[7] Plaintiffs argue that Dr. Morris's testimony should be excluded because he relies on only "short term" studies (meaning "less than one year," as defined by Plaintiffs in their brief) and failed to cite any "long-term" studies showing low Bard IVC filter fracture rates. (Pls. Mot. at 5-7.) Plaintiffs again fail to acknowledge that Dr. Morris addressed the studies on which Plaintiffs' experts rely in his report and his deposition. Additionally, in his report, Dr. Morris cites Mitsunaga, *et al.*, *Fracture Rate and Serious Complications of Vena Cava Filters*, 3 Open J. of Radiol. 85-90 (June 2013), attached as Exhibit H, which reports a 0% fracture rate for the 57 Bard's filters analyzed. (*Id.* at 85; Ex. A, MDL Report at 26.) That study was a 10-year retrospective analysis, and the mean indwell time for the Bard IVC filters reviewed was 19.0 ± 16.6 months with a range up to 49.5 months. (*See* Ex. H, Mitsunaga, *et al.*, at 85.)

[8] Implicit in Plaintiffs' argument is the suggestion that their medical experts ***did*** review internal Bard documents in forming their opinions, making them reliable. But in many instances, Plaintiffs' medical experts merely reviewed reports of other Plaintiffs' experts, which provide snippets or summaries of Bard's internal documents, and not the actual documents themselves. (*See, e.g.*, Dr. David Streiff Dep. Tr., attached as Exhibit I, at 100:12-22; Dr. Desai Dep. Tr., attached as Exhibit J, at 41:11 to 42:7; 52:2-14.) In another instance, Plaintiffs' expert reviewed another expert's report that cited internal company documents, and only then did the expert request to see a subset of documents cited in the report. (*See* Dr. Vogelzang Dep. Tr., attached as Exhibit K, at 81:15-24.)

Advance Am., 278 F.R.D. 562, 566 (S.D. Cal. 2011) ("[T]he court considers whether the evidence is a type that is reasonably relied upon by experts in the field.").

Internal company documents are not the type of information that medical practitioners, including interventional radiologists, reasonably rely on to form treatment opinions. As Dr. Morris explained, when forming clinical opinions in the course of his medical practice, he relies on peer-reviewed literature, not internal company documents. (Ex. B, Morris Dep. at 252:8-22.) Thus, in his practice, he has not reviewed internal company documents to form his medical opinions. (*Id.* at 252:23 to 253:7; 254:12 to 255:1.)

Dr. Morris is not alone in how he develops his medical opinions. Indeed, his practice is consistent with various medical doctors who place IVC filters, including those who implanted filters in the bellwether plaintiffs in this MDL. For instance, Dr. Roderick Tompkins, who placed Bellwether Plaintiff Debra Mulkey's filter, testified that during the course of his medical practice, no medical device company has ever shown him its internal documents or draft emails. (*See* Dr. Roderick Tompkins Dep. Tr., attached as Exhibit L, at 183:11-18 ("Q. During the course of your practice, has any medical device company ever shown you their internal documents? A. No. Q. During the course of your practice, has any internal -- any medical device company ever shown you a draft e-mail? A. No.").) Similarly, Dr. Shanon Smith, who implanted Bellwether Plaintiff Carol Kruse's filter, testified that he has never been shown internal company documents from a product manufacturer. (*See* Dr. Shanon Smith Dep. Tr., attached as Exhibit M, at 142:19-23 ("Q. Okay. And prior to today, have you ever been shown internal documents from any product manufacturer? A. Not that's been presented to date that I'm aware of."); *id.* at 143:11-17 ("Q. (BY MS. HELM) Okay. Before 2110 was handed to you today -- A. Uh-huh. Q. -- have you ever been handed any internal documents from any product manufacturer for products that you use? A. No.").) Bellwether Plaintiff Doris Jones's implanting physician, Dr. Anthony Avino, provided similar testimony. (*See* Dr. Anthony Avino Dep. Tr.,

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attached as Exhibit N, at 96:9-11 ("Q. Do you typically see internal documents of that type from any other manufacturer of any device? A. No.").)

Moreover, Plaintiffs' own medical experts testified that they do not typically receive or rely on internal company documents in their own medical practices. For example, Plaintiffs' interventional radiology expert, Dr. Sanjeeva Kalva, testified as follows:

> Q. Prior to your involvement in this litigation, have you ever had an instance professionally to read a manufacturer's internal documents as a part of your work?
> A. No. Except for the IFUs that come on the products, I have not been exposed to internal documents. I wish I was, to know the truth. But unfortunately they were not communicated with me.
> Q. And so throughout your professional career, this is the first time you have looked at or analyzed internal company documents from a manufacturer, correct?
> MR. JOHNSON: Form.
> A. That is correct.

(Dr. Sanjeeva Kalva Dep. Tr., attached as Exhibit O, at 28:18 to 29:6.)[9]

Courts have disapproved of medical experts' reliance on internal company documents in forming medical opinions about a product. *See Soldo v. Sandoz Pharm.*

[9] (*See also* Ex. I, Dr. Streiff Dep. Tr. at 101:3-8 ("Q. Okay. Outside, I guess, of the IVC filter litigation and outside of Dr. Kessler's report and reviewing Dr. Garcia's deposition and the exhibits, you have not previously ever reviewed internal, internal company documents? A. No."); Ex. K, Vogelzang Dep. Tr. at 84:18-22 ("Q. Just so the record's clear, Doctor, as you sit here today you can't tell me about any other IVC manufacturer, IVC filter manufacturer's internal documents that you have seen other than Bard? A. I don't have a specific recollection."); Dr. David Garcia Dep. Tr., attached as Exhibit P, at 84:11 to 85:2 (Dr. Garcia testified that he "never had occasion" or "opportunity" to review internal company documents before he became involved in this litigation); Dr. Thomas Kinney Dep. Tr., attached as Exhibit Q, at 84:4-8 ("Q. During the course of your practice, has any medical device company, other than medical device companies who you may have had a formal consulting agreement with, ever showed you their internal documents? A. No."); Dr. Darren Hurst Dep. Tr., attached as Exhibit R, at 116:13-17 ("Q. Other than a medical device company that you were consulting for, has any other medical device company shown you their internal documents? A. No."); Dr. Anne Roberts Dep. Tr., attached as Exhibit S, at 123:15 to 124: 9 ("Q. During the course of your medical practice, has any medical device company showed you their internal documents? A. I guess -- you mean internal e-mails or -- Q. E-mails, presentations, memoranda. . . . THE WITNESS: Not that I can recall. I don't -- I can't think of internal memos or e-mails that I would have seen.").

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Corp., 244 F. Supp. 2d 434, 545 (W.D. Pa. 2003) (excluding medical expert's causation opinion, finding that medical expert's opinions based on an internal company document that could not be published in a peer-reviewed publication could not form the basis of a reliable opinion); *Glastetter v. Novartis Pharm. Corp.*, 252 F.3d 986, 991 (8th Cir. 2001) (affirming decision to exclude the plaintiff's experts who relied, in part, on internal company documents taken out-of-context regarding alleged link between defendant's drug and stroke); *Caraker v. Sandoz Pharm. Corp.*, 172 F. Supp. 2d 1046, 1052-53 (S.D. Ill. 2001) (following conclusions of *Glastetter*). *Cf. In re Mirena*, 169 F. Supp. 3d at 426 ("The statements and public positions of Bayer are not scientific literature that an expert would be expected to confront in the exercise of intellectual rigor in the field.").

Finally, Plaintiffs argue that Bard's internal documents conflict with Dr. Morris's opinions, and his failure to review those documents renders his opinions unreliable. (*See* Pls. Mot. at 9-10.) This precise argument was soundly, and rightly, rejected by the MDL judge in *In re Mirena*. As that court succinctly stated, "Defendants' experts' failure to confront alleged conflicting statements made by Bayer does not warrant exclusion under *Daubert*." *In re Mirena*, 169 F. Supp. 3d at 427. Instead, the court concluded, "[p]otentially conflicting statements by Bayer personnel are irrelevant for purposes of this *Daubert* motion." *Id.* at 419.

4. Plaintiffs Simply Disagree with Dr. Morris's Opinions.

Plaintiffs' disagreement with Dr. Morris's opinions does not render them unreliable or inadmissible under *Daubert*. "[T]he test under *Daubert* is not the correctness of the expert's conclusions but the soundness of his methodology." *Primiano*, 598 F.3d at 564 (9th Cir. 2010) (citing *Daubert I*, 509 U.S. at 594, 596). "Alternative or opposing opinions or tests do not preclude the admission of the expert's testimony-they go to the weight, not the admissibility." *Moore v. Breg, Inc.*, No. CV-09-027-TUC-DCB, 2011 WL 7395094, at *2 (D. Ariz. Oct. 20, 2011) (internal quotation marks omitted).

Plaintiffs' argument is, in essence, that Dr. Morris's opinions are unreliable simply because they conflict with Plaintiffs' purported interpretation of the available data and

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medical literature. (*See, e.g.*, Pls. Mot. at 10 (arguing that Dr. Morris's opinion is "controverted by both the literature and Bard's own recommendations"); *id.* at 15 (arguing that Dr. Morris's opinion "is contrary to the literature").) But the law in the Ninth Circuit is clear that a court's task is "to analyze not what the experts say, but what basis they have for saying it." *Daubert II*, 43 F.3d at 1316. As demonstrated above at Section A.1, Dr. Morris's opinions are based on a sound, scientific methodology that is employed by other medical professionals, including Plaintiffs' own medical experts. His opinions are reliable and should not be excluded in this case.[10]

B. Plaintiffs Misstate and Mischaracterize Dr. Morris's Opinions About Imaging and Follow-Up and the Bases for Those Opinions.

In attempting to undercut Dr. Morris's opinions about the use of imaging and patient follow-up, Plaintiffs misstate and mischaracterize his opinions. Furthermore, an analysis of certain of the material upon which Plaintiffs rely reveals that their authorities actually support Bard's position and Dr. Morris's opinions.

[10] Plaintiffs cite law that is not supportive of their position. Plaintiffs primarily rely on broad propositions from *Daubert I* and its progeny that offer little to no insight into their arguments. (*See generally* Pls. Mot.) Also, Plaintiffs accuse Dr. Morris of "first identifying his conclusion," "cherry picking," and "litigation selection bias," (Pls. Mot. at 5, 8), but the cases they cite are not on point. For example, in *In re Bextra & Celebrex Mktg. Sales Practices & Prod. Liab. Litig.*, 524 F. Supp. 2d 1166 (N.D. Cal. 2007), the court addressed "the use of epidemiology to prove causation" between Celebrex and heart attacks and strokes. *Id.* at 1172. In the portion of the opinion relied upon by Plaintiffs, the court held that a plaintiff's expert's opinion that the lowest dosage of Celebrex could cause heart attacks was not based on "good science." *Id.* at 1176. The court offered pages of reasons for this conclusion, including: 1) the expert was not qualified to give an epidemiological opinion, 2) the expert arrived at his opinion only after being retained as an expert, 3) many of the other plaintiffs' experts disagreed, 4) the expert had a "fundamental misunderstanding" of the primary study on which he relied, and 5) the expert's opinion was based in part on extrapolating data from studies on higher doses of Celebrex. *Id.* at 1176–81. None of those reasons exist here. Plaintiffs' other authorities are similarly inapposite. *See, e.g.*, *In re Toyota*, 978 F. Supp. 2d 1053 (court excluded opinion of expert that the findings of the National Highway Traffic Safety Administration are biased toward finding mechanical and driver error as the cause of sudden unintended acceleration); *In re Countrywide Fin. Corp. Mortg.-Backed Sec. Litig.*, 984 F. Supp. 2d 1021 (C.D. Cal. 2013) (court excluded testimony based on a sampling methodology where 90% of the loans included in the sample were at issue in the litigation); *In re Phenylpropanolamine (PPA) Prods. Liab. Litig.*, 289 F. Supp. 2d 1230, 1250 (W.D. Wash. 2003) (court excluded opinion that an ingredient in cough/cold medications could cause a wide array of cardiac injuries due to "some thirty-five different biological mechanisms").

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Plaintiffs mistakenly assert that Dr. Morris opines that "filters that have been in place long-term do not need imaging or medical monitoring follow-up." (Pls. Mot. at 1; *see also id.* at 15 ("[Dr. Morris] concludes that imaging and follow-up are unnecessary for patients having filters in longer than one year.").) Similarly, Plaintiffs state that Dr. Morris claims "that the use of imaging during follow-up is unnecessary." (*Id.* at 10.) These incomplete statements mischaracterize Dr. Morris's opinions on the importance of clinical follow-up with patients with IVC filters and the role of imaging.

1. Dr. Morris Believes That IVC Filter Patients Should Be Clinically Assessed.

At no point has Dr. Morris opined that clinical follow-up of patients with IVC filters is unnecessary. In fact, his opinion is the polar opposite. Dr. Morris opines that "[p]atients should be 'clinically reassessed periodically' to determine if and when their IVCF should be removed." (Ex. A, MDL Report at 6.) Contrary to Plaintiffs' assertion, (*see* Pls. Mot. at 11, 13), Dr. Morris's opinions are 100% consistent with Bard's IFU, which notes SIR's recommendation that patients with IVC filters receive "routine follow-up," and with FDA's 2014 Safety Communication, which recommends that physicians responsible for follow-up care of patients with IVC filters consider removing the filter when it is no longer needed. (*See* Bard Denali® Filter IFU, attached as Exhibit T; Ex. E, 2014 FDA Safety Communication.) Notably, neither Bard's IFU nor the FDA's Safety Communication makes any recommendation for routine imaging (much less a routine non-contrast CT scan as proposed by Plaintiffs) simply to check on the status of the device prior to a decision being made that a filter should be retrieved.

2. Dr. Morris Believes That Asymptomatic Patients Do Not Require Routine Medical Imaging as Part of Their Follow-Up Care.

Dr. Morris does not opine that the use of medical imaging in the follow-up care of an IVC filter patient is never proper in any scenario. To the contrary, Dr. Morris makes clear that "[i]f a patient with an IVCF has a symptom at any time, such as abdominal pain, then a contrast enhanced CT scan may be warranted." (Ex. A, MDL Report at 15.) Of

course, whether a patient requires imaging to determine the potential source of a physical symptom will depend on the patient's medical history, course of treatment, and the physician's clinical practices.

Dr. Morris's opinion that medical imaging should not be part of a routine follow-up protocol for an otherwise asymptomatic patient with an IVC filter is well-supported by the literature. Indeed, in his report, Dr. Morris cites 12 peer-reviewed medical articles that provide examples of systematic protocols (including the protocols used at his practice and at Northwestern, where Plaintiffs' interventional radiology experts practice) for methods to follow-up with patients with IVC filters. (*See* Ex. A, MDL Report at 12 & Refs. 6, 53-63.) None of these protocols includes routine CT scans or other medical imaging merely to check on the status of a patient's IVC filter prior to a decision being made that a filter should be retrieved.

3. Plaintiffs Mischaracterize the Literature.

Plaintiffs argue that Dr. Morris's opinion "fails to recognize" certain literature that they claim supports their argument that all patients with a Bard IVC filter should receive routine imaging to check on the status of their filters. (Pls. Mot. at 11.) An assessment of Plaintiffs' authorities reveals that they do not support their arguments.

i. The SIR *Reporting Standards*

Plaintiffs argue that Dr. Morris ignored SIR's "*Reporting Standards*"[11] for IVC filter placement and follow-up, which "recommend 'minimum objective testing' of the filter during follow-up, which [according to Plaintiffs] includes 'imaging of vena cava prior to retrieval.'" (Pls. Mot. at 11.) Dr. Morris explained that these "*Reporting Standards*"—as the name strongly suggests—are just that: standards for physicians to follow when they are ***reporting*** in the medical literature on their usage of IVC filters. (Ex. B, Morris Dep. at 262:7-16.) They are not "Practice Parameters"—such as the ones cited

[11] *See, e.g., Recommended Reporting Standards for Vena Cava Filter Placement and Patient Follow-up*, 30 J. Vasc. Surg. 573-79 (1999), attached as Exhibit U; *Recommended Reporting Standards for Vena Cava Filter Placement and Patient Follow-Up*, 14 J. Vasc. Radiol. S427-S432 (2003) ("*Reporting Standards*"), attached as Exhibit V.

by Plaintiffs in their Motion at Exhibit 23—in which the SIR, along with other medical organizations, makes recommendations for practicing clinicians to follow for the placement and management of IVC filters. (*Id.*) A closer review of the *Reporting Standards* makes their context clear and reveals that Plaintiffs' use of brief snippets from the *Reporting Standards* is misleading.

As a preliminary matter, it should be noted the SIR's *Reports Standards* have been published four times, but Plaintiffs tellingly only cite the versions from 2003, 2005, and 2009.[12] (Pls. Mot. at 11.) The first version was published in 1999 before retrievable filters were commercially available and three years before Bard's first retrievable filter was introduced. (*See* Ex. U, 1999 *Reporting Standards* at 576 ("There are no currently approved temporary (must be removed) or optional (may be removed) vena cava filters in the United States.").) The 2003 version of the *Reporting Standards* contains the exact same statement that optional filters did not exist in the United States at the time the 2003 *Reporting Standards* was written. (*See* Ex. V, 2003 *Reporting Standards* at S429.) The first brief snippet that Plaintiffs quote—"minimum objective testing"—is found only in the 1999 and 2003 publications, which addressed only permanent filters. (*See* Ex. U, 1999 *Reporting Standards* at 575; Ex. V, 2003 *Reporting Standards* at S429.) Therefore, Plaintiffs cannot credibly represent that SIR meant for this three word quote to be a specific recommendation about retrievable filters, much less Bard retrievable filters. Additionally, the second snippet quoted by Plaintiffs—"imaging of vena cava prior to retrieval"—only appears in the 2005 and 2009 publications, and, thus, it is completely untethered to "minimum objective testing."[13] (*See* Ex. W, 2005 *Reporting Standards* at

[12] *See Reporting Standards for Vena Cava Filter Placement and Patient Follow-up: Supplement for Temporary and Retrievable/Optional Filters*, 16 J. Vasc. Interv. Radiol. 441-43 (2005), attached as Exhibit W; *Reporting Standards for Vena Cava Filter Placement and Patient Follow-up: Supplement for Temporary and Retrievable/Optional Filters*, 20 J. Vasc. Interv. Radiol. S374-S376 (2009), attached as Exhibit X.

[13] The 2005 and 2009 *Reporting Standards* are self-titled "supplements" to the prior publications, and they specifically address "Temporary and Retrievable/Optional Filters." If Plaintiffs claim that the language "imaging of vena cava prior to retrieval" in the 2005 and 2009 publications is a recommendation that routine imaging should be performed on in-dwelling retrievable filters, context belies this conclusion. As shown in the image

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442; Ex. X, 2009 *Reporting Standards* at S375.) Imaging "prior to retrieval" (for example, an ultrasound done immediately before retrieval to assess whether there is clot in a filter) is a far different concept than imaging as a part of routine patient follow-up, and Plaintiffs' attempt to conflate two very different points, set forth in different versions of the standards, is not an accurate reading of the *Reporting Standards*.

The 1999 and 2003 *Reporting Standards* are replete with indications that their main goal is to provide a guide so that information about filters can be reported in the literature in a consistent way. They begin by noting, "The literature contains hundreds of reports . . . for patients who have had [IVC filters] placed but the reports do not employ consistent standards, definitions, or techniques, making it difficult to compare outcomes and determine the relative efficacy and safety of the available devices." (Ex. U, 1999 *Reporting Standards* at 573; Ex. V, 2003 *Reporting Standards* at S427.) The *Reporting Standards* then provide substantial detail for how physicians should document and report their studies, and they clearly contemplate studies of multiple subjects. (*See, e.g.*, Ex. U, 1999 *Reporting Standards* at 575; Ex. V, 2003 *Reporting Standards* at S429 ("When [patient follow-up] ***is reported***, the number of patients followed should be compared to the

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below, Plaintiffs pulled the quote from a box entitled "Reporting Criteria for Filter Retrieval" that contains a list of seven items:

Reporting Criteria for Filter Retrieval

1. Anticoagulant medications: Specify type and duration of use
2. Implantation period
3. Filters not retrieved: Specify reasons
4. Site of venous access for retrieval
5. Imaging of vena cava prior to retrieval: Include imaging technique, position of filter and trapped emboli
6. Complication or technical difficulty during retrieval: Describe any additional equipment or techniques used
7. Imaging of vena cava following retrieval: Include imaging technique and evidence of vena caval injury

(Ex. W, 2005 *Reporting Standards* at 442; Ex. X, 2009 *Reporting Standards* at S375.) Moreover, Plaintiffs have truncated the language they quote. The full quote is "5. Imaging of vena cava prior to retrieval: Include imaging technique, position of filter and trapped emboli." (Ex. W, 2005 *Reporting Standards* at 442; Ex. X, 2009 *Reporting Standards* at S375.) The only logical reading of this list is that if a filter retrieval is performed as part of a published paper, the *Reporting Standards* recommend that the authors of the paper record and report the seven listed items.

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total number of filters placed at each institution during ***the period of the report***."); Ex. U, 1999 *Reporting Standards* at 576; Ex. V, 2003 *Reporting Standards* at S427 ("Outcome data should be based on ***samples of sufficient size*** to support clinical conclusions. Actual numbers, not just percentages, should be included."); Ex. U, 1999 *Reporting Standards* at 576; Ex. V, 2003 *Reporting Standards* at S427 ("Clinical studies are currently in progress and we ***urge that study results be reported according to these recommendations to facilitate fair evaluation***.").) Finally, the *Reporting Standards* note the "data should be evaluated with use of rigorous statistical methods" (2003 *Reporting Standards* only) and that "adherence to these guidelines . . . will allow ***the combination of reports from multiple sites*** and provide a better level of evidence upon which to base future recommendations." (Ex. U, 1999 *Reporting Standards* at 576; Ex. V, 2003 *Reporting Standards* at S427.) This quoted language clearly demonstrates that Dr. Morris has a solid basis under a *Daubert* analysis to buttress his opinion disputed by Plaintiffs that the *Reporting Standards* are "recommendations for clinicians to study filters, and not necessarily meant to follow patients clinically with these recommendations." (Pls. Mot. at 11.)[14]

ii. Duffett, *et al.* and Kuo, *et al.*

Plaintiffs also selectively quote from Duffett, *et al.*[15] as alleged support for their position that Dr. Morris ignored literature that advocates for routine medical imaging of IVC filter patients. (Pls. Mot. at 12.) But that article actually supports, not refutes, Dr.

[14] Medical literature—including an article written by Northwestern University colleagues of Plaintiffs' experts Drs. Vogelzang and Desai—further supports Dr. Morris's opinion that the SIR *Reporting Standards* are intended to be used as a guide for uniform reporting in the literature. (*See, e.g.*, Dhand, *et al.*, *The Role of Potentially Retrievable Inferior Vena Cava Filters in High-Risk Patients Undergoing Joint Arthroplasty*, 9(12) J. of Clin. and Diag. Res. TC01-TC-03 (Dec. 2015), attached as Exhibit Y, at TC01 ("Data were collected according to the Society of Interventional Radiology (SIR) reporting standards for IVC filter placement and follow-up."); Yamagami, *et al.*, *Venous Thromboembolism After Removal of Retrievable Inferior Vena Cava Filters*, 33 Cardiovasc. Interv. Radiol. 74-79 (2010), attached as Exhibit Z, at 75 ("In this retrospective study, data for analysis were obtained through review of each patient's chart and results of analysis are described according to the reporting standards recommended in [the SIR *Reporting Standards*].").)

[15] *Inferior Vena Cava Filters*, 15 J. Thrombosis & Haemostasis 3 (2017), attached as Exhibit AA.

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Morris's opinion that IVC filter patients should be clinically assessed, and that imaging may be used if the patient is symptomatic. Plaintiffs rely on the following quotation: "In patients where the filter remains in place, close follow-up to assess removal and screening for filter complications, such as strut fracture, embolization, and IVC occlusion, should be considered." (*Id.*) The authors write, however, on the very same page: "Follow-up and screening for [filter-related] complications remain unclear. Suggested follow-up has been ***clinical evaluation*** for signs of recurrent DVT or post-thrombotic syndrome. ***Objective imaging of the filter can be obtained if clinical symptoms develop***." (Ex. AA, Duffett, *et al.* at 9.) And, in direct contravention of Plaintiffs' proposal that all Bard IVC filter patients should receive medical imaging as part of routine follow-up, the authors state, "The need for routine diagnostic imaging (ultrasound, computerized tomography or angiography) of the filter in the absence of clinical findings ***remains undetermined***." (*Id.*)

Finally, Plaintiffs cite Kuo, *et al.*,[16] which calls for "close monitoring" of patients, and the 2016 SIR Practice Parameters (Pls. Ex. 23), which calls for IVC filter patients to be "clinically reassessed." (Pls. Mot. at 12.) Like Bard's IFU and the 2014 FDA Safety Communication, these authorities actually support Dr. Morris's opinion that IVC filter patients should be clinically assessed to determine their continued need for IVC filtration, and they make ***no mention*** of a purported need for patients to receive routine, pre-removal imaging merely to check on the status of their filters.[17]

Plaintiffs try to twist Dr. Morris's opinions into something they are not, and in doing so, repeatedly mischaracterize the authorities upon which they rely. Ultimately, Dr.

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[16] *Complex Retrieval of Fractured, Embedded, and Penetrating Inferior Vena Cava Filters: A Prospective Study with Histologic and Electron Microscope Analysis*, 24 J. Vasc. Interv. Radiol. 622 (May 2013), attached as Exhibit 22 to Plaintiffs' Motion.

[17] The ***only*** article that supports Plaintiffs' theory that all patients (not just those who are part of a clinical study) with IVC filters should receive medical imaging as part of their routine follow-up is Hull, *et al.*, *Bard Recovery Filter: Evaluation and Management of Vena Cava Limb Perforation, Fracture, and Migration*, 20 J. Vasc. Interv. Radiol. 52 (Jan. 2009), attached as Exhibit 10 to Plaintiffs' Motion. Plaintiffs' expert Dr. David Bates agrees. (*See* Dr. David Bates Dep. Tr., attached as Exhibit BB, at 52:18-23; 53:20-23; 55:7-14.) Dr. Morris considered and addressed the Hull, *et al.* article. As Dr. Morris points out, the Hull, *et al.* paper studied only 14 subjects, which is "very small and cannot provide statistical significance." (Ex. A, MDL Report at 26.)

Morris's opinions regarding recommended IVC filter patient follow-up are entirely consistent with the applicable medical literature, Bard's own recommendations, and FDA's recommendations, and there is no basis for their exclusion.

III. CONCLUSION

Dr. Morris bases his opinions in this case on his over 25 years of clinical experience as an interventional radiologist. His opinions are buttressed by the available medical literature. Dr. Morris considered the same type of data he considers when making clinical decisions in his medical practice, including contradictory medical literature, in reaching his opinions. His opinions are the product of the "ordinary methodology of evidence based medicine." *Primiano*, 598 F.3d at 567. Therefore, his opinions should not be excluded, and Plaintiffs' Motion should be denied.

DATED this 27th day of September, 2017.

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CERTIFICATE OF SERVICE

I hereby certify that September 27, 2017, the foregoing was electronically filed with the Clerk of Court using the CM/ECF system which will automatically send e-mail notification of such filing to all attorneys of record.

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